

DETAILED ACTION

Response to Amendment

1. The amendment to the specification filed 1-5-10 has not been entered because such does not comply with 37 CFR 1.121 in that all the changes made to the previously existing paragraph bridging pages 9-10, i.e. the originally filed paragraph, have not been shown, e.g. trademarks added not underlined. Therefore see the following paragraph 3.

Information Disclosure Statement

2. The references cited by applicants in the information disclosure statements filed 9/09 and 1/13/09 have been made of record. Examiner has considered the voluminous references to the best of her ability.

While MPEP § 2004 sets forth guidelines regarding both the number of references cited and the elimination of clearly irrelevant art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR §§1.97 and 1.98 do not require that the information be material; rather, they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references. However, the cloaking of a clearly relevant reference by inclusion in a long list of citations may not comply with Applicant's duty of disclosure. *See Penn Yan Boats, Inc. v. Sea Lark boats Inc.*, 359 F. Supp. 948, *aff'd* 479 F. 2d. 1338.

Applicant is advised that the MPEP states the following with respect to large information disclosure statements:

Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more is highly relevant to patentability. MPEP § 609.04(a)(III).

This statement is in accord with dicta from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), states that forcing the Examiner to find “a needle in a haystack” is “probative of bad faith.” *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888.

The MPEP provides more support for this position. In a subsection entitled “Aids to Compliance With Duty of Disclosure,” item thirteen states:

*It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F.Supp 948 (S.D. Fla. 1972) *aff'd* 479 F.2d 1338 (5th Cir 1974). See also MPEP § 2004.*

Therefore, it is recommended that if any information that has been cited by Applicants in the previous disclosure statements is known to be material for patentability as defined by 37 CFR § 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

Specification

3. The use of the trademark TEGADERM and OPSITE FLEXIGRID, page 10, lines 2-3, has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Trademarks should be in all capital letters or with the trademark symbol, not both. Note MPEP 608.01(v), I., paragraph 6-20 therein, Examiner Note 1 thereof.

Claim Rejections - 35 USC § 112

4. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, at the very least, the description of the at least one discrete opening as being “uncovered at the top surface” on line 9 but “configured to be directly open to an undermined portion of the wound such that negative pressure is communicated to the undermined portion of the wound directly from the at least one discrete opening” on lines 9-11 is still unclear/inconsistent, e.g. the undermined portion of the wound covers the opening at the top surface. This also applies to similar language on lines 10 and 16-18 of claim 9. It is noted that Applicant’s remarks refer to the language of lines 3-4, not the lines relied upon by Examiner. Also again it is noted the claim language does not require “uncovered at the top surface” to being

uncovered or unobstructed by any other structure or component of the claimed member. The deletion of the language “uncovered” in claim 1 and in claim 9 and the insertion of --each-- before “adapted” on the second to last line of claim 9 is suggested. With regard to claim 8, at the very least, the description of “substantially all of” the generally planar bottom surface directly engaging the top surface of the wound contactable layer on lines 11-12 but “cooperating with the channels extending along the top surface of the wound contactable layer to define a plurality of passageways” on lines 12-13 is unclear/inconsistent, i.e. if it cooperates with channels along the top surface to define passageways how can it directly engage “substantially all of” the surface, i.e. surface includes channels as described (Note the portion of the top surface directly engaged thereby is only that between/without channels “along such surface”). Also with regard to claim 1, at the very least, the description of the cover as being “generally non-porous” on line 7 but having “at least one discrete opening extending through a top surface of the cover” on line 9 is unclear/inconsistent (Note the definition of “porous” and “pore”, see PTO-892, and the lack of claiming of any specific dimensions of the at least one opening). This rejection also applies to similar language in claim 9.

Claim Language Interpretation

5. Since no claim language has been explicitly defined, such terminology will be given it broadest reasonable interpretation in light of the specification, e.g. its dictionary definition. Therefore, the terminology “channel” is defined by the dictionary not only as “a trench furrow or groove” but also as “a tubular passage for liquids” as well as “a course or passage through which something may be moved or directed”. Therefore, and also due to the lack of clarity discussed in

the preceding paragraph, “a generally non-porous cover” is interpreted to require “a generally non-foam like/non-foam cover”, see page 5, lines 25-27 of the application as originally filed. Due to the lack of clarity discussed in the preceding paragraph, claims 1 and 9 are interpreted to require the discrete opening/holes at the top surface be “uncovered” sometime, e.g. prior to use, but configured to be directly open to an undermined portion of the wound such that negative pressure is communicated to the undermined portion of the wound directly therefrom also at sometime. Due to the lack of clarity discussed supra, claim 8, lines 11-12 will be interpreted to require a generally continuous bottom surface with no projections extending directly therefrom which extends between an outer perimeter of the cover and some portion thereof is directly engaged with the top surface of the wound layer.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Risk Jr. et al ‘807, and thereby, by incorporation, Lockwood et al ‘681.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claim 1: See the Claim Language Interpretation section, hereinafter also referred to as CLI, as well as '807 at, e.g., Figure 9 and col. 9, line 66-col. 10, line 59, and thereby, by incorporation, '681, i.e. the member is 604 and 618, the wound contactable layer is 604 having a bottom surface which is adapted to be in contact with and generally conform to the wound surface, the "discrete" holes are 614 extending through the bottom surface thereof, the "generally non-porous", see CLI, cover is 618 which includes at least one "discrete" opening, see 618 in Figure 9 between lines thereof and, e.g., col. 10, lines 35-43, i.e. non-foam/non-foam like, extending through the top surface thereof, see Figure 9, and the port is 620 which is configured to communicate with the vacuum source and in fluid communication with each "discrete" hole and the at least one "discrete" opening (It is noted that "communicate" includes direct and/or indirect communication). As discussed supra claim 1 now also requires the at least one discrete opening extending through a top surface of the cover be "uncovered", see CLI supra, and configured to be directly open to an undermined portion of the wound at the top surface such that negative pressure is communicated to an undermined portion of the wound directly from the at least one discrete opening, i.e. the structure of the opening has the capability, property or function of opening directly to an undermined portion of the wound at the top surface such that negative pressure is communicated to an undermined portion of the wound directly from the at least one discrete opening. See again Figure 9 as well as col. 10, lines 35-43 and discussion supra. Therefore, since '807 teaches the claimed structure as well as such being capable of communicating a negative pressure therethrough, i.e. communicates directly therefrom to the area therearound, and placement in a wounds, i.e. the capability of contacting and conforming to wound surfaces (note also '681 and sentence bridging cols. 6-7), at the very least, there is

sufficient factual evidence for one to conclude that such same structure also inherently includes the same capability, property or function as claimed, i.e. the structure of the opening has the capability, property or function of opening directly to an undermined portion of the wound at the top surface such that negative pressure is communicated to an undermined portion of the wound directly from the at least one discrete opening at sometime, see MPEP 2112.01.

Claim 2: See the Claim Language Interpretation section supra, i.e. the definition of “channels”, and the portions of ‘807 cited supra, i.e. the “channels” of the upper surface are 606, see also Figures of ‘681 incorporated by ‘807, and the cover 618 has a bottom surface which engages with the top surface of the wound contactable layer and cooperates with such channels to define a plurality of passageways between the port and each discrete hole and between the port and the at least one discrete opening as claimed, see Figure 9 and col. 10, lines 35-43. It is noted that the claim does not require each of the passageways being a discrete passageway between the port and each hole or between the port and each opening.

Claim 3: See the Claim Language Interpretation section supra and Figure 9 of ‘807 and Figure 7 of ‘681, i.e. a surface area of the cover, e.g. the engaged surface of the packing, e.g., the center of 618/bottom surface 58, is smaller than a surface area, e.g. the top surface of 604/20, i.e. of the wound contacting layer, so that layer 604/20 and thereby, the “channels”, e.g. 606/28/30, extend beyond an outer edge of cover 618/58 and define a plurality of the “discrete” openings, i.e. such “channels” at the top surface thereof laterally beyond the engaged surface of the packing.

Claim 4: See the Claim Language Interpretation section supra, the discussion of claim 1 supra and Figure 9 again, i.e. ‘807 teaches the cover includes more than one of the discrete

openings through the top surface thereof, i.e. the apertures of packing 618, in communication with channels 606/28/30.

Claim 5: See the discussion of claims 1, 2 and 4 supra.

Claim 6: See the Claim Language Interpretation section supra and the discussion of the claims supra, i.e. '807 teaches the claimed structure and a cover including a outer peripheral portion (It is noted that no specific dimension of such portion is claimed nor the specific relationship of such with regard to the remaining portions of the cover is claimed) and such cover including at least two openings which are closer to the periphery or edge than other openings or the center point, see Figure 9.

Claim 7: The terminology "relative thin and flexible" is considered relative absent the claiming of specific dimensions of thinness and flexibility. See also '807 at the portions cited with respect to claim 1 and thereby, also '681 at, e.g., col. 4, lines 50- col. 11, lines 54-57, e.g. layers described as "thin" and "flexible" and "of gauze". Therefore the member is also considered to be "relatively thin" and "flexible".

Claim 8: See the discussion of claims supra with regard to lines 1-10 and 12 et seq and the discussion infra of the claim language with regard to lines 10-12. Claim 8 now claims the cover having a generally continuous planar bottom surface which extends between an outer perimeter of the cover wherein substantially all of the surface is directly engaged with the top surface of the wound contactable layer, as best understood, see CLI supra. Therefore also see '807 at the cited portions, esp. Figure 9 and paragraph bridging cols. 9-10 and thereby, e.g., '681 at Figure 7, i.e. as best understood, the cover includes a generally continuous bottom surface

with no projections extending directly therefrom which extends between an outer perimeter of the cover and some portion thereof is directly engaged with the top surface of the wound layer.

Claims 9 -11: See the discussion of claims supra, esp. 1, 6 and 7.

Response to Arguments

8. Applicant's remarks have been considered but are either deemed moot in that the issue has not been reraised or deemed not persuasive for the reasons set forth supra. Specifically the remarks with respect to the prior art are narrower in scope than the claim language, as best understood, see CLI, and/or the teachings of the prior art and/or the rejections relying thereon, see paragraph 7 supra.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any new grounds of rejection were necessitated by the amendments to claims 1, 8 and 9.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karin M. Reichle/
Primary Examiner, Art Unit 3761

April 5, 2010